Remarks

Upon entry of this Amendment, claims 1-3, 5-9 and 12 remain pending. Claim 1 is amended herein, while claims 4, 10 and 11 have been cancelled without prejudice or disclaimer. Entry of the amendment to claim 1 and reconsideration and allowance of all pending claims in view of the remarks below are hereby requested.

Rejections under 35 U.S.C. §102

Claims 1, 6 and 11 are rejected under 35 U.S.C. §102(b) as being anticipated by Tu, et al., U.S. Patent No. 5,061,276. Applicants traverse this rejection.

Claim 1 has been amended to recite that the ridges are spaced apart to direct a needle to a puncture site at an angle. The spaced apart distance is approximately less than or equal to 1.5 times the outer diameter of the needle. Applicants note that this limitation does not involve new matter, as this limitation was contained in previous claim 4. Applicants therefore request entry of this Amendment.

Applicants submit that claim 1 is not obvious in view of U.S. Patent No. 5,061,276 to Tu et al. Numbered paragraph 6 on page 3 of the Office Action asserts that the spaced apart distance being less than or equal to 1.5 times the outer diameter of the needle is a design consideration within the realm of one ordinary skill in the art. Applicants traverse this assertion. On page 6, at lines 15-18, Applicants' specification states that Applicants have determined that a spaced-apart distance D of approximately less than or equal to 1.5 times the outer diameter of the needle is effective to direct the needle between the ridges at an angle that inhibits needle plowing and hole enlarging.

Applicants note that the Tu reference does not teach or suggest such a consideration. Furthermore, Applicants dispute that such a spaced-apart distance is merely a design consideration, as the specific beneficial functionality as described by Applicants is provided by such a spaced apart distance. "To be anticipating, a prior art reference must disclose 'each and every limitation of the claimed invention[,]...must be enabling[,] and [must] describe...[the] claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the filed of the invention.' *In re Paulsen*, 30 F.3d 1475, 1478-79, 31 USPZ2d 1671, 1673 (Fed. Cir. 1994)." *Helifix Ltd. v. Block-Lok, Ltd*, 208 F.3d 1`339, 54 USPZ2d 1299 (Fed. Cir. 2000).

In view of the above remarks, Applicants submit that claim 1 is patentable over Tu. Applicants submit that dependent claim 6 is patentable at least by way of its dependency from claim 1. Applicants note that claim 11 has been cancelled.

Rejections Under 35 U.S.C. §103

Claims 4, 7, and 12 are rejected under 35 U.S.C. §103(a) as being unpatentable over Tu *et al.* (U.S. Patent No. 5,016,276). Applicants traverse this rejection in view of the remarks below.

Regarding claim 7, Applicants traverse the assertion in numbered paragraph 7 on page 3 of the Office Action that the feature of having the nodes at a 90 degree angle with respect to the winding axis would be a matter of obvious design choice. The Office Action asserts that Applicant has not provided evidence that the stated angle provides any advantage, nor that any unexpected result would arise from the configuration disclosed

by Tu. Applicants traverse this assertion and respectfully direct the Examiner's attention to the specification at page 7, line 26 to page 8, line 7. Specifically, Applicants indicate that they have determined experimentally that orienting the nodes forming the microstructure of the membrane generally at an angle other than 0 degrees relative to the winding axis results in improved bonding with a support structure while concomitantly minimizing delamination of the support structure during needle puncture. "The mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claims is not by itself sufficient to support a finding of obviousness. The prior art must provide a motivation or reason for the worker in the art, without the benefit of appellant's specification, to make the necessary changes in the reference device." *Ex parte Chicago Rawhide Manufacturing Co.*, 223 USPQ 351, 353 (Bd. Pat. App. & Inter. 1984). As such, Applicants assert that claim 7 is patentable over Tu. Furthermore, Applicants assert that claim 7 is patentable at least by way of its dependency from claim 1.

Applicants assert that claim 12 is patentable over Tu, for at least the reasons described above in relation to the discussion of claim 1. Specifically, claim 12 recites that the spaced apart distance is less than 1.5 times the outer diameter of the needle. As discussed in greater detail above, Applicants assert that this is not merely a design consideration and again direct the Examiner's attention to the specification at page 6, line 15-18.

As noted above, claim 4 has been cancelled.

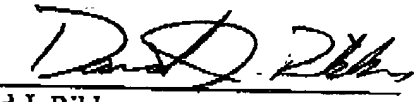
Claims 2-3, 5, and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al. (U.S. Patent No. 5, 016,276) in view of Martakos et al. (U.S. Patent No. 5,897,587). Applicants traverse this rejection. Applicants submit that claims 2-3, 5 and 8-9 are patentable at least by way of their dependency from claim 1.

Conclusion

In view of the remarks set forth above, it is respectfully submitted that this application is in condition for allowance. Accordingly, allowance is requested. If there are any remaining issues or the Examiner believes that a telephone conversation with the Applicants' attorney would be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned at (617) 227-7400.

Respectfully submitted,

LAHIVE & COCKFIELD, LLP

By: 
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Dated: **June 19, 2003**

U.S. Serial N . 09/903,374
Group Art Unit # 3764

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Please amend claim 1 as follows. Please cancel claims 4, 10 and 11 without prejudice or disclaimer.

1. (Twice Amended) A prosthesis for surgical implantation to replace a segment of a blood vessel, the prosthesis comprising:

a first tube of biologically compatible material having an exterior surface,

a membrane of polymer material positioned about the exterior surface of the first tube, and

at least one support structure wound along a winding axis about an exterior surface of the membrane to form axially spaced-apart ridges on the membrane that enable the material to substantially close a hole that is created when the material is punctured by a needle or cannula, the membrane having a microstructure of nodes interconnected by fibrils effective to facilitate bonding of the support structure to the membrane and inhibit delamination of the support structure from the membrane;

wherein the ridges are spaced apart a distance effective to direct a needle to a puncture site at an angle that inhibits needle plowing and hole enlarging, the spaced apart distance being approximately less than or equal to 1.5 times the outer diameter of the needle.

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Group Art Unit # 3764

IN THE SPECIFICATION:

On page 6 please amend the second full paragraph to read:

The support structure 16 is wound along a winding axis A about the membrane 14 at a winding angle W relative to the longitudinal axis L of the prosthesis 10. The winding angle W is preferably greater than 0° and can be up to 90°, as is the case when the support structure 16 is a ring or plurality of rings. The support structure 16 is preferably wound at a winding angle or pitch W such that the ridges 18 are spaced apart a distance, indicated by arrow D in Figures 1 and 3, effective to direct a needle to a puncture site at an angle that inhibits needle plowing and hole enlarging. Applicants determined that a spaced-apart distance D of approximately less than or equal to [than] 1.5 times the outer diameter of the needle is effective to direct the needle between the ridges 18 at angle that inhibits needle plowing and hole enlarging.